DAY ONE:

8:00 – 8:15 - Registration and Continental Breakfast

8:15 – 8:30 - Welcome and Introduction

8:30 – 9:30 - How to Satisfy 46.111 Criteria for Approval Including Protections for Vulnerable Populations
Michelle Brignac, CIP, CHRC, OHSP Coordinator III, Office of Human Subjects Protection, St. Jude Children’s Research Hospital
Ms. Brignac will address various dilemmas in consenting vulnerable populations. The session will look at three case studies and identify tools that can help to ensure the rights and welfare of subjects are protected. As a result of the session, attendees will be able understand 45 CFR 46.111 and the challenges to consent vulnerable populations and identify tools to help the participant in the consent process.

9:30 – 10:30 - A Changing IRB World
Brian Stage, CIP, Research Compliance Consultant for Regulatory Affairs, Reliance, and Outreach, Indiana University Human Subjects Office
The Revised Common Rule has been in effect for a little over a year now. Researchers have probably noticed changes to the way they are interacting with their IRBs. Mr. Stage will discuss the changes that have had the biggest impact on researchers, why their IRBs made those changes, and what other changes they should look out for in the future.

10:30 – 10:45 - Break

10:45 – 11:45 - An overview of the Law and its Impact on Clinical Research
Sheila Sokolowski, JD, Partner, Hogan Marren Babbo & Rose, Ltd
Ms. Sokolowski will provide an overview of the law and the American legal system. It will include history and evolution and the interplay between law and research.

11:45 – 12:45 - Lunch (Provided)

12:45 – 1:45 - REDCap Versatility of use: Unique solutions for commonplace problems
Dirk Orozco, BS, Associate Application Specialist, Vanderbilt University Medical Center
Storage and maintenance of study related documents is paramount especially when managing multiple studies. Mr. Orozco will discuss best practices and how the Vanderbilt Coordinating Center utilizes REDCap to address study related challenges. Focusing on operational and personnel management utilizing REDCap databases in a format easily reviewed by monitors for compliance study compliance.

1:45 – 2:45 - EConsent: Moving Towards Personalized Informed Consent
Leah Dunkel, MPH, Research Services Consultant, Vanderbilt University Medical Center
In an effort to address issues of transparency, appropriate patient understanding/research literacy, clinical trial efficiency, and regulatory compliance around informed consent, we have created a suite of tools within the REDCap software platform centered around meaningful collection and storage of electronic consent (eConsent). This eConsent framework seeks to provide a more personalized consent experience whereby users may be guided though a web-based consent document that utilizes avatars, contextual glossary information supplements, videos, images, text reader functions, branching questions for comprehension, and other features that can facilitate communication of information to patients in a culturally relevant manner respective of health literacy level. Ms. Dunkel will focus on describing the features of the eConsent platform, how to specifically build an eConsent, and how eConsent features can be used to support customization for the benefit of prospective participants.

2:45 – 3:00 - Break

3:00 – 4:30 - Challenges in the Conduct of Clinical Research
Elizabeth L Guy, BSN, CCRP, Clinical Research Supervisor, Office of Clinical Research- UC Davis Comprehensive Cancer Center
Conducting clinical research present numerous challenges. In this interactive session attendees will discuss and identify challenges in the conduct of clinical research in different scenarios and settings/organizations. Learners will analytically discuss solutions or resolutions to the identified challenges.
DAY TWO:

8:00 – 8:15 - Continental Breakfast

8:15 – 9:15 - The Informed Consent Process and the Role of the Research Participant Advocate

Wendy Hayes, MSN, RN, CPHON, Research Participant Advocate, Office of Human Subjects Protection, St. Jude Children’s Research Hospital

It is not good enough that we just inform possible participants of the required information about research studies. We must also ensure understanding. Ms. Hayes will detail the informed consent process and describe the role and responsibilities of the Research Participant Advocate during this discussion. As a result of attending this session, attendees will understand the required elements of an informed consent discussion and be able to describe the role and responsibilities of the Research Participant Advocate.


Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP, Director of BioSafety Services, Advarra

Gene therapy is a quickly growing area of research as the U.S. and other countries have begun issuing approvals. Recent regulatory changes, scientific advances and demographics have combined to create ideal conditions for a boom in gene therapy research, particularly in oncology. Mr. Eisenman will provide an introduction to the field of gene therapy research and discuss the evolving regulatory environment as well as strategies for institutions interested in conducting gene therapy research, including considerations for IRB and IBC review.

10:15 – 10:30 - Break

10:30 – 11:30 - Implementing the Ethical Principle of Justice: Policy and Practical Implications of Including Women and Minorities in Research

Cynthia Davis PhD, Associate Center Director, Clinical Trials Operations Cooperative Studies Program, Massachusetts VA

Dr. Davis will reference the Belmont Reports principle of justice. She will explain how it mandates the equitable selection of subjects for research. An ethical and scientific argument will be made to justify the inclusion of women and minorities in research. Some of the policy and practical implications of including women and minorities in research will also be discussed.

11:30 – 12:30 - Lunch (Provided)

12:30 – 1:30 - Ensuring Patient Safety Through Risk Based Monitoring

Jamie Harper, MHA, CCRP, Director of Clinical Research, Illinois CancerCare, P.C

In the changing environment of clinical research, there are areas in every research program where patient safety is at a higher risk. Ms. Harper will discuss these areas and provide tips on how to mitigate the risk through auditing techniques. This discussion will also review some process improvement tools that can be used in conjunction with risk based auditing.

1:30 – 2:30 - Training as Part of Compliance

Gail Mayo, RN, CCRP, Research Nurse Specialist, Vanderbilt University Medical Center

Ms. Mayo will discuss the merging of why, who, what, where, when and how of protection of human research participants, compliance and training. Attendees will discuss practical approaches to training in the realm of research practice.

2:30 – 2:45 - Break

2:45 – 3:30 - Case Study: Research Fraud: Does the Punishment Fit the Crime?

Wendy Lloyd, BA, LPN, CCRP, Senior Clinical Quality Research Analyst, Vanderbilt Institute for Clinical and Translational Research

What if we change this one finding? What if we enroll a subject who barely misses the applicable inclusion criteria? Who will ever know? Ms. Lloyd will present research Fraud case studies to promote discussion surrounding consequences for the researcher, the research community and research subjects.